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Endoluminal Repair of Abdominal Aortic Aneurysm—Contemporary Australian Experience

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Objective. *An audit was established in November 1999 by the Australian Government Department of Health and Ageing to determine the mid- to long-term safety and efficacy of endoluminal graft repair (ELG) of abdominal aortic aneurysm (AAA). The audit has been undertaken by the Australian Safety and Efficacy Register for New Interventional Procedures—Surgical (ASERNIP-S). This study reviews contemporary Australian practice, based on audit data supplied to ASERNIP-S.*
Design of study. *This study is a prospective voluntary register (audit) of Australian data obtained from the private and public sector. Data were collected for ELG repairs performed between 1 November 1999 and 16 May 2001. Follow-up is continuing.*
Results. *Seventy-nine vascular surgeons have contributed data on 950 patients (816 male, 134 female, of median age 75.5 (range 36–94)). The mean aneurysm size was 57.5 mm (±10.2) and 44% of procedures were performed on aneurysms less than 55 mm in diameter. Fifty four percent of patients were considered suitable for open repair.*
Most ELG procedures were performed in an angiography or endovascular suite, under general anaesthetic using an open technique via the femoral arteries. Perioperative mortality was 1.7%, mostly from cardiac causes. Prior to discharge 7.2% of patients experienced an endoleak and 18.6% had systemic complications. The average length of stay was 7.4 days (median 5 days). Unsuccessful exclusion of the aneurysm occurred in 6.7% of cases.
Conclusions. *Endovascular repair of AAAs is a well accepted procedure and is performed by the majority of vascular surgeons in Australia. Australian surgeons are taking a rather aggressive approach to the management of aortic aneurysms, particularly in the moderate to higher risk patient groups. Mortality rates are low, given the elderly population in question and morbidity rates acceptable. ASERNIP-S is continuing to collect follow-up data for this patient cohort.*

Key Words: Aortic aneurysm; Abdominal-surgery; Australia; Medical audit; Vascular surgical procedures.

Introduction

Endoluminal graft (ELG) repair of AAA was first reported in 1991 by Parodi *et al*.[1] During the next few years important contributions to the application of this technique were made by two Australian groups.[2] In 1992, a group in Sydney led by J. May and G. White at the Royal Prince Alfred Hospital started performing ELG repair and have subsequently reported on a number of stent-graft systems. In 1993, a group in Perth led by M. Lawrence-Brown and D. Hartley deployed their first stent-graft, which is now called the Zenith graft (Cook Australia Pty, Brisbane, Australia), and is the most commonly used graft in Australia. During the last decade ELG repair has been widely adopted within Australia and is currently performed by the majority of vascular surgeons.

With the introduction of ELG repair came the requirement to show that the grafts were safe and durable.[3] In 1999 the Australian Government Department of Health and Ageing agreed to fund a national audit, on the proviso that at least 95% of all privately performed elective procedures were collected. Data were also to be collected for procedures performed in the public sector. The Australian Safety and Efficacy Register of New Interventional Procedures—Surgical (ASERNIP-S) established the audit, which has now been in progress for over three years.

This review aims to give an overview of the current role of ELG repair in contemporary Australian vascular practice.

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Method

ASERNIP-S is a programme of the Royal Australasian College of Surgeons (RACS), which has been funded to audit ELG repair and assess the medium to long-term results of the procedure. An audit reference group comprising vascular surgeons with a high level of expertise in the endoluminal procedure advises ASERNIP-S on clinical aspects of the procedure. Approval for the audit was obtained from the Ethics Committee for the Royal Australasian College of Surgeons.

Data were requested from surgeons for endoluminal procedures performed between the 1 November 1999 and 16 May 2001. Additional data were requested at discharge/early follow-up and ongoing follow-up for each patient at 6 months, 12 months then annually thereafter. Data are submitted either on paper forms or using a secure online data entry system through the ASERNIP-S web site. National aggregate results of the audit are distributed to participating surgeons.

Results presented here were taken from the operative and discharge data sets, in order to develop an overview of contemporary practice of ELG repair, with particular reference to indications, technique and initial results. The following clinico-pathological data were collected: age, gender, presence/absence of co-morbidities, aneurysm diameter and morphology, preoperative imaging modalities, operative and anaesthetic techniques, type of graft, peri-operative mortality, intra-operative and post operative complications, early endoleak (based on intraoperative angiography and postoperative CT scan), duration of post operative hospital stay. The American Society of Anaesthesiology (ASA) classification was used to assess patient fitness for surgery. Peri-operative mortality was defined as death within 30 days of the procedure.

Surgeons were asked to decide prior to the procedure, whether the patient was suitable for open repair and possible randomisation to a trial of open versus endovascular repair. Technical and clinical success rates were calculated according to reporting standards established by the Ad Hoc Committee for standardized reporting practices in vascular surgery.[4]

Results

Up to 1 August 2003, a total of 950 ELG procedure patients were enrolled in the audit of which 70% ($n = 667$) were performed in the private sector and the remainder in the public system. The 667 private patients represented around 87% of all procedures performed privately in Australia. Discharge/30 day information was received for 930 (98%) patients. Fifty four percent ($n = 895$) of patients were considered suitable for potential randomisation to a trial of open or endovascular surgery. The volume of ELG surgery performed and ultimately submitted to ASERNIP-S remained constant at around 50 cases per month.

Surgeon participation

Seventy-nine surgeons have contributed to the audit; the number of procedures performed by each surgeon is shown in Fig. 1. According to information provided by the Health Insurance Commission, there were approximately 18 surgeons who performed fewer than five private procedures during the period of the audit, but did not submit their data to the ASERNIP-S. Some of these procedures may have been submitted under an alternative surgeon's name. Thus it appears that over 90 vascular surgeons (i.e. over 65% of those in active practice) perform the procedure on a regular or occasional basis.

Anatomical features

Mean aneurysm diameter was 57 mm ($\pm$ 10.2). Where maximum aneurysm diameter was reported ($n = 921$), a total of 44% ($n = 407$) of aneurysms measured less than 55 mm in diameter, with 27% ($n = 253$) $\leq$ 50 mm in diameter.

In terms of morphology, 69% (582/841) of aneurysms did not extend beyond the aortic bifurcation and a further 20% (167/841) had good iliac 'landing zones' proximal to the iliac bifurcation. Few cases had difficult distal anatomy (approximately 4%). Twenty-five percent (212/859) of patients had a 'neck' length less than 20 mm and only 9% (81/859) were less than 15 mm. Eleven percent (105/950) of patients had

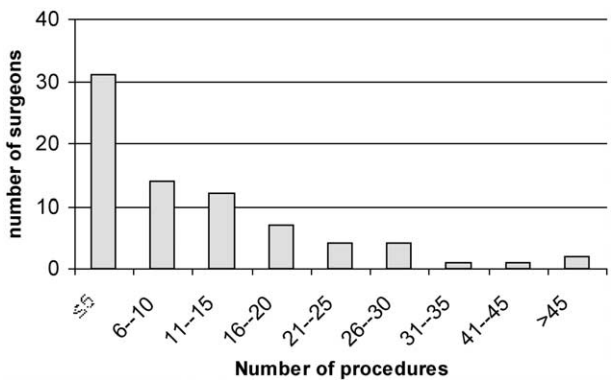

Fig. 1. Number of ELG procedures performed by Australian vascular surgeons.

thrombus in the neck of the aneurysm and 20% had a saccular aneurysm. Thirteen percent (124/950) of patients were recorded with an aortic neck angle ≥45°, 1.5% (14/950) of patients were recorded with an aneurysm angle ≥60°.

Age and patient fitness

Most patients in the audit are male (86%, $n = 816$). The mean age (±SD) of patients enrolled in the audit is 75.0 ± 6.9 years. Fifty-seven percent ($n = 538$) of patients are 75 years or older, 34% ($n = 345$) fall within the 65–74 years bracket and 7% ($n = 67$) are less than 65 years.

Overall, 33% of patients were categorised as ASA I or II, 59% as ASA III and 6% as ASA IV. For patients groups with an aneurysm diameter less than 55 and ≤50 mm, 44% had an ASA of I or II, 54% had an ASA of III and 2% had an ASA of IV (Table 1).

Imaging

Imaging done pre-operatively most commonly included both spiral CT and angiography. The most typical combination was spiral CT and angiography (58%, $n = 539/932$), but these two imaging techniques were used in combination with other imaging techniques in a further 20% of cases. Angiography was used in 83% of cases. Spiral CT on its own accounted for 11% ($n = 99/932$) of imaging.

Surgical details

Most procedures were performed in an angiography or endovascular suite (67%, 609/910); the rest were performed in an operating theatre. Around 74% (680/922) of procedures were performed under general anaesthesia, and epidural/spinal anaesthesia was used in 26% (235/922) of cases. The most commonly used main access vessel is the femoral artery (96%, 897/934), and access is usually open (92%, 855/930) rather than percutaneous. The main type of graft used in Australia during the period of audit was the Zenith graft (Cook Australia) (83%, 785/946). The use of other graft types was: Ancure (Guidant) 1.5% ($n = 14$), AneuRx(Medtronic) 6.5% ($n = 62$), Excluder (W L Gore) 4.3% ($n = 41$), Talent (World Medical) 3.7% ($n = 35$), and Vanguard (Boston Scientific) 0.7% ($n = 7$). The aorto-bi-iliac-bifurcated design is the most common configuration (92%, 865/938).

Technical and clinical success

(Assisted) primary technical success was 89.7% ($n = 853$) and secondary technical success increased this to 92.8% ($n = 883$). It was not possible to distinguish between planned and unplanned additional endovascular and surgical procedures performed at the time of ELG deployment. Thirty day clinical success was 86.8% ($n = 825$).

Length of hospital stay

The mean length of stay (±SD) for patients undergoing endoluminal stent repair is 7.4 (±8.8) days.

Mortality

Peri-operative mortality was 16/950 (1.7%). The main cause of death was cardiac-related (43%, $n = 7$), however, neurological and intra-abdominal complications accounted for a further 7 deaths.

Ten of the 16 perioperative deaths were amongst patients who were not considered suitable for open repair (2.4%, $n = 410$). Five perioperative deaths occurred in patients whose aneurysms measured less than 5.5 cm (1.2%, $n = 408$).

Procedural complications

Graft related complications included failed access, access vessel complications, failed and misplaced deployment of endografts, imperfect seal, twist/kink/obstruction and embolisation. The overall rate for these complications was 13.7% ($n = 131$), with

Table 1. ASA classification and aneurysm size

	Aneurysm size (mm)	Number of subjects	Percent of aneurysms of that size (%)
ASA I or II	<55	175	44
ASA III	<55	212	54
ASA IV	<55	9	2
ASA I or II	≤50	108	44
ASA III	≤50	131	54
ASA IV	≤50	6	2

imperfect seal accounting for 5.3% ($n = 51$) of these (Fig. 2). Prior to discharge a further 12 cases (1.2%) of graft migration or thrombosis were noted. For patients whose aneurysms measured less than 5.5 cm the graft related complication rate was 10.5% ($n = 43/408$). Seventy complications were noted for patients who were unsuitable for open repair (17%, $n = 410$).

Surgeons noted a range of systemic complications with an overall rate (excluding pyrexia) of 18.6% ($n = 177$); the leading cause attributed to cardiac-related complications (7.2%, $n = 69$). Access site and lower limb complications were experienced by 7.8% ($n = 74$) of patients, with bleeding, haematoma and false aneurysm being the major grouping (3.8%, $n = 36$). Sixty patients with aneurysms less than 5.5 cm experienced systemic complications (14.7%, $n = 408$) and 109 patients unsuitable for open repair had systemic complications (26.6%, $n = 410$).

Additional procedures

A number of patients had additional procedures during the same hospital admission period. At the time of the procedure, 23.5% ($n = 223$) of patients had an additional endovascular procedure, 3.1% ($n = 30$) had an additional surgical procedure and 0.9% ($n = 9$) were converted to an open procedure. After surgery but prior to discharge a further 2.1% ($n = 20$) of patients required further surgical interventions (10 open, 7 endovascular and 3 'other').

Endoleaks

Predischarge type I endoleaks were reported in 2.6% ($n = 25$) of cases and type II endoleaks in 4.6% ($n = 44$) of cases. Surgeons reported unsuccessful exclusion in 4.5% (41/919) of procedures, however, this increased to 6.7% (64/950) when the reported incidence of failed access, failed deployment and type 1 endoleak (prior to discharge) were included.

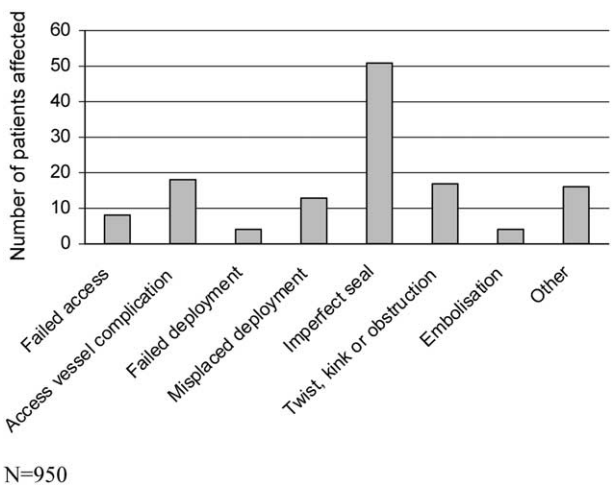

Fig. 2. Graft related complications.

Discussion

Endoluminal graft repair (ELG) has rapidly become a widely adopted procedure in the armamentarium of vascular surgeons in Australia. This article aims to review the indications for the procedure amongst Australian vascular surgeons and initial outcomes.

The cases submitted constitute 87% of all procedures performed privately in Australia for the audit period. Results for this procedure have been re-appraised every 6-months and there has been little overall change as more patients have been added to the database, indicating that the data set is robust and stable. However, the indicators and outcomes of the remaining 13% of private cases are unknown.

The results suggest that older and sicker patients are being treated with endoluminal grafts. Surprisingly, a large number of aneurysms (27%, $n = 253/921$) are being treated that are ≤ 50 mm diameter and 44% ($n = 407$) are less than 55 mm in diameter. Fifty six percent of both patient size groups ($\leq$ and <55 mm) are ASA III or IV. Conversely, a large number (44%) of smaller aneurysms (≤ 50 mm) are being treated in relatively healthy patients (ASA I or II) with ELG, possibly due to the perceived low risk of the procedure by many Australian surgeons.

Recently published guidelines for the treatment of AAAs by a subcommittee of the Joint Council of the American Association for the Vascular Surgery and Society for Vascular Surgery recommend an intervention threshold of 55 mm in the 'average risk' patient and possible lower threshold in younger fitter patients and women.[5] The guidelines also recommended delayed repair until larger aneurysm diameters are reached for higher risk patients.

Clearly Australian surgeons are taking a rather aggressive approach to the management of aortic aneurysms, particularly in the moderate to higher risk groups. Despite treating an elderly population with a significant number of comorbidities, reported mortality was low (1.7%) and morbidity rates (systemic, 19%, graft related, 13%) were acceptable. Failure to exclude the aneurysm due to failed access, failed deployment or early type I endoleak occurred in 6.7% of cases.

During the audit period, 58% of patients underwent spiral CT and angiography prior to ELG repair. A total

Table 2. Comparisons between the Australian audit data and EUROSTAR

	EUROSTAR[6–10]	Australian data
Perioperative mortality	1.7–2.6%	1.7%
Conversion to open	1.0–1.7%	1%
Graft migration	0.3–2%	0.5%
Endoleak (discharge)	16%	7%
Systemic complications	12–18%	23%
Cardiac	3–5%	7%
Pulmonary	1.8–3%	5%
Renal	2–3%	3.6%
Cerebral	0.7–1.5%	2.0%
Hepatobiliary	0.1–0.3%	0.3%
Male	91–95%	86%
Age (mean)	71	75.0
Aneurysm size (mean)	57 mm	57 mm
ASA I	7–9%	3%
ASA II	35–39%	31%
ASA III	44–45%	58%
ASA IV	6–7%	6.5%
Study period	1996–2003	1999–2001
Zenith (Cook) endografts	1-33%	83%

EUROSTAR: $N = 1554$[6–10]$–4242$.[10]

of 83% underwent angiography. With current rapid advances in non-invasive imaging, it is likely that fewer (if any) patients will require invasive imaging in the future. In this audit period only 11% of patients underwent CTA without angiography as their work up.

The majority of surgeons in Australia perform $<$10–15 ELG procedures per year which suggests that they are using the procedure selectively—offering it to a sicker and/or older patient population or those with a 'hostile' abdomen, and perform open repair on healthier patients. A cohort of surgeons offers the procedure to all patients with suitable anatomy.

Table 2 compares Australian data with that published for EUROSTAR. Eurostar initiated its data collection in 1996. The Australian data represents a substantial proportion of Zenith (Cook, Australia) endografts (83%) and compares with an incidence of 1% in the early Eurostar collection; however, this has increased to 33% in the more recent data.[10]

In conclusion, our experience suggests that the operative Australian data is robust, having changed little as extra patients have been added to the audit. As the length of study increases, so too will the usefulness of the data in assessing outcomes. Thus far, Australian data compares favourably with that published elsewhere. The long-term data will help to evaluate the durability of this generation of endografts. By feeding results back to surgeons the results may also help to inform practice regarding suitability of treatment for specific patients.

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